7. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is being submitted in accordance with the requirements of The Safety Medical Device Act of 1990 and 21 CFR Part 807.92

510(k) Number: K022802

Date of Summary Preparation:
August 6, 2002

OCT 16 2002

Submitter: Applied Biotech, Inc.
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Manufacturing Site: Applied Biotech, Inc.
10237 Flanders Court
San Diego, California 92121
Phone: 858-587-6771
Establishment Number: 2028231
Device Trade Name: DrugFree@Home™: THC Test
Device Common Name: THC testing system
Device Classification: Class II (21 CFR 862.3250)
Device Product Code: LDJ
Performance Standards: None established (as a medical device) under Section 514.
Device Description: One step immunoassay for the detection of THC in urine.

Intended Use The DrugFree@Home™: THC Test is an *in vitro* diagnostic screen for the detection of THC in urine. The DrugFree@Home™: THC Test has a cutoff concentration of 50ng/mL. The DrugFree@Home™: THC Test is used to obtain a visual, qualitative result and in intended for over-the counter sale to laypersons.

Indication for Use The DrugFree@Home™: THC Test is an *in vitro* diagnostic screen test for the rapid detection of 11-nor-Δ^9-THC-9-COOH in human urine at above a concentration of 50ng/mL. The test provides a preliminary analytical result, and if necessary, a pre-paid confirmation test (GC/MS) is included. The DrugFree@Home™: THC Test is used to obtain a visual, qualitative result and in intended for over-the counter sale to laypersons.

Substantial Equivalence Claim to:
DrugFree@Home™ THC/COC (07/03/2001 K002253).

Technology: The DrugFree@Home™: THC Test uses a one-step sandwich immunoassay technology based on the immunochemical principal of recognition and formation of specific antibody/target drug/antibody/complexes.

Performance: The DrugFree@Home™: THC Test for home use was evaluated in a consumer accuracy study by comparing consumer test results against GC/MS reported values. The study resulted in 95% agreement between the consumer test results and the GC/MS reported values

Conclusion: For the reasons mentioned above, it may be concluded that the DrugFree@Home™: THC Test is substantially equivalent to commercially available OTC devices for home use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Applied Biotech, Inc.
c/o Ms. Vivianne Noetzel
Noetzel Terratech
P.O. Box 9433
Rancho Santa Fe, CA 92067

OCT 16 2002

Re: k022802
Trade/Device Name: DrugFree@Home™ THC Test
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: LDJ
Dated: August 6, 2002
Received: August 23, 2002

Dear Ms. Noetzel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. INDICATIONS FOR USE STATEMENT

510(k) Number: K02 2 8 0 2

Device Name: DrugFree@Home™: THC Test

Indication for Use

The DrugFree@Home™: THC Test is an *in vitro* diagnostic screen test for the rapid detection of 11-nor-Δ^9-THC-9-COOH in human urine at above a concentration of 50ng/mL. The test provides a preliminary analytical result, and if necessary, a pre-paid confirmation test (GC/MS) is included. The DrugFree@Home™: THC Test is used to obtain a visual, qualitative result and in intended for over-the counter sale to laypersons.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022802

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓